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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,581	01/18/2002	Syed Riauddin Hashmi	455.1005	6351

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,581	HASHMI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,9,12,15-19,22 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,9,12,15-19,22 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted March 28, 2005 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5, 9, 15-19, 22, 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "a selection of vitamins and minierals" in the claims lacks support from the application as originally filed. Example 7 herein merely provides a specific selection of minierals and vitamins, and does not support the general statement herein.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "trace quantities" in claim 36 is a relative term which renders the claim indefinite. The term "trace quantities" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. The claims are indefinite as to the amounts of the vitamins and miniral encompassed thereby.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 12, 15-19, 22, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFarlane et al (NZ 270754, IDS) in view of Dupont et al. (6,028,1 18), Bath et al. (6,333,304), and in further view of Cochran (6,048,846) and Francis (3,683,080).

The instant invention is directed toward a composition comprising at least one anti-inflammatory agent selected from green-lipped mussel extract or shark cartilage, and at least one enhancing agent selected from a bark product, a bark extract, or shark cartilage, wherein for a composition including just one member from each group, the selected members must be different.

McFarlane et al teaches an anti-inflammatory composition comprising. New Zealand green-lipped mussel extract and a fish oil, particularly useful for treating arthritis. The composition has synergistic effect as compare the individual ingredients therein. See the entire documents

McFarlane et al. does not teach expressly a composition comprising green-lipped mussel extract, Shark cartilage, and bark extract.

However, Dupont et al. teach a method of treating arthritis by administering an extract of shark artilage. The shark cartilage is taught as having anti-angiogentic and anti-inflammatory activities. See Col. 28, lines 48-56. Bath et al. teach treatments for arthritis in animals, including non-human animals. Pine bark extract is taught as scavenging free radicals, inhibiting mast cell degranulation (cause of inflammatory response), reducing histamine release (cause of inflammatory response), and inhibiting enzymes that break down collagen and elastin, thereby stopping the deterioration of joints, and quelling inflammation. See Col. 8, lines 13-26, Col. 5, lines 24-40.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make an composition useful for treating arthritis comprising green-lipped mussel extract, bark extract and shark cartilage and to use the same for treating inflammatory condition, such as arthritis in mammals, including non-human animals.

A person of ordinary skill in the art would have been motivated to make an composition useful for treating arthritis comprising green-lipped mussel extract, bark extract and shark cartilage and to use the same for treating inflammatory condition, such as arthritis in mammals, including non-human animals because it is prima facie obvious to combine two or more compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their

having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. Additionally, it would have been obvious to add the shark cartilage extract of Dupont et al. to the composition of McFarlane because of the expectation of enhancing blood flow to the suffering area. Furthermore, it would have been obvious to add the pine bark extract of Bath et al. to the composition of McFarlane et al. because of the expectation of stopping the deterioration of the joint, quelling inflammation, and stopping free radical damage. Further, making a therapeutical composition into a well-known form, such as tablet, capsule, is within the skill of artisan. Finally, a therapeutical agent broadly known to be useful for treating arthritis, would have reasonably expected to be useful for both human and non-human animals. The employement of the minerals and vitamins herein recited in the compositions is obvious because it is well known that vitamins and minerals, as nutrients, provide benefit for subject suffering inflammatory conditions, such as arthritis. See, columns 6-18 in Cochran, and columns 6-8 in Francis. The optimization of a result effective parameter, e.geffective amounts of known therapeutical agents or duration of a therapy, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over McFarlane et al (NZ 270754, IDS) in view of Dupont et al. (6,028,1 18), Bath et al. (6,333,304), and in further view of Cochran (6,048,846) and Francis (3,683,080) as applied to claims 1, 5, 12, 15-19, 22, 35-38 above, and further in view of Church (Velvet Antler: It's Historical Medical Use).

McFarlane, Dupont et al. Bath et al. Cochran and Francis are applied as discussed above. The references lack deer velvet.

Church teaches that in 1996, researchers at the University of Alberta demonstrated that

glycosaminoglycans in the water soluble fractions of velvet antlers have growth promoting effects on cells, and anti-inflammatory properties. See "Review of Scientific Literature on Elk Velvet Antler"

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add deer velvet, as taught by Fisher et al, to the composition of the combined references because of the expectation of achieving a composition that further combats the inflammatory response, thereby easing arthritis.

Response to the Arguments

Applicants' amendments and remarks, and the declaration by Sabina A. Holle have been fully considered, but are not persuasive.

7. The declaration under 37 CFR 1.132 filed March 28, 2005 is insufficient to overcome the rejection of claims 1, 5, 9, 12, 15-19, 22, 35-38 as set forth above because:

It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., without fish oil) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note the phrase "comprising" and "containing" are open to any further ingredients. Further, McFarlan et al. disclosed that green-lipped mussel extract individually has been known to be useful for treating arthritis.

Applicants assert an unexpected and surpriisng increase in efficacy, but fail to provide evidence for supporting the assertion. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The evidences must be *clear and convincing*. The claims must be *commensurate in the scope* with any evidence of unexpected results. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.132 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e).

8. It is noted that the last page of the specification is not in English. A proper correction is required.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
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Art Unit 1617